≤18kg in 7/11). At baseline 6 patients were NYHA Class II and 5 were Class III. Clinical procedural success was achieved in 9/11. One patient experienced a major ischemic stroke (MRS=3 at discharge; final 90-day adjudication pending). A second had a mean post-procedure gradient of 22mmHg (above the 20mmHg VARC threshold) although the valve was functioning well (post-procedure AVA 1.6cm2). Partial resheathing was performed in 4/4 patients; none required full retrieval. Mean aortic gradient was 53.9±20.9mmHg at baseline and 13.7±3.7mmHg at discharge. Mean AVA was 0.7±0.2cm^2 at baseline and 1.5±0.2cm^2 at discharge. Paravalvular AR was mild in 2 patients, trivial in 1, absent in 8. Conduction disturbance requiring a new pacemaker occurred in 4 patients (2 with complete AV block). There were no deaths or MIs through 7 days.
Conclusions: Early feasibility results suggest that the Lotus Valve can be positioned precisely and successfully with virtually no AR and low clinical event rates through discharge, supporting further study in a larger, more rigorous trial. Three-month data will be presented for the first time at TCT 2012.

Interventional Innovation: Novel Therapies and the "Best" New Device Concepts for 2012

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TCT-105

Long-term Intravascular Blood-Pressure Monitoring with a Novel, Wireless Sensor System – Results from Chronic In-vivo Studies

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Background: Long-term blood-pressure (BP) monitoring is a vital necessity for physicians to prescribe appropriate medical treatment for malign hypertension patients in order to reduce the incidence of secondary consequences such as stroke, kidney failure or heart insufficiency. However, current devices are still not suited for long-term measurement (several weeks to months). Moreover, they usually measure the peripheral blood pressure which significantly differs to the central blood pressure known to be the better indicator for vascular diseases. In order to address this need, we developed and conducted in-vivo tests on a novel, fully-implantable, wireless blood-pressure monitoring system.
Methods: The monitoring system was tested for six months in 12 chronic ovine models. The sensor was implanted with X-ray-control in the femoral artery by means of a dedicated sheath (PASIS). Reference measurements were recorded with gold standard pressure sensors after implantation. Position and proper functioning of the sensor were controlled via regular readout measurements and CTs. At the end of each trial, a histological examination was conducted.
Results: Chronic in-vivo studies revealed that blood pressure measurement over a period of six months was possible with the novel implantable sensor system. Stable pressure histories were recorded. However, the mechanical resilience of the sensor system requires improvement. The in-vivo tests in the femoral artery of sheep produced high stress on the sensors system. Several implanted systems became inoperative despite efforts to stiffen the sensor-cable. The histological analysis detected no thrombi. Mild inflammatory reactions were found at the vessel insertion site in several cases.
Conclusions: The results of the chronic in-vivo tests on the novel fully-implantable blood-pressure monitoring system were encouraging. Improvements need to be made regarding the mechanical resilience of the system and the coating. Additional trials at a modified implantation spot will be conducted in order to reveal further insights regarding system performance.

TCT-106

BioInnovate Ireland: A Multidisciplinary Approach To Medical Device Innovation

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Background: A 10 month research program; to find and validate a relevant unmet clinical need in cardiovascular care prior to developing solutions.
Methods: A multidisciplinary team of four members with experience in clinical medicine, engineering, business and software design received four weeks' training in basic anatomy, physiology, market analysis, clinical needs finding and concept generation, intellectual property (I.P.), regulatory, reimbursement and business planning. The fellows jointly agreed an acceptance criteria e.g. market size, measurable endpoints etc to aid future decision making. For eight weeks the team were attached to tertiary care hospitals to understand the patient cycle of care and the perspectives of all the stakeholders impacting in/out-patient care and to observe a range of in-hospital procedures. This resulted in nearly 2000 observations which were translated into 120 problem statements. These problems were researched in terms of incidence, prevalence, disease pathophysiology, existing treatments effectiveness, market size etc. This insight and filtering against the acceptance criteria enabled further elimination. The remaining problems were translated into clinical needs statements and validated by speaking to key stakeholders, in-depth medical literature review and competitor analysis. As a result eight needs statements emerged. The resultant concepts from brainstorming of the needs were screened against agreed need specifications and pre-existing I.P. Further literature and primary research, filtering and elimination led to a final need entitled: A cost effective, fast way to embolize a blood vessel. This had emerged from observing that current embolization devices are deficient e.g. need for multiple coils, migration, recanalization, and high prices.
Results: Funding was successfully applied for and secured from Enterprise Ireland to enable prototyping with proof of concept via bench testing and animal studies.
Conclusions: This multidisciplinary innovation research program brings together the key stakeholders involved with medical devices and enables the development of a rich network and expertise that will promote patient care through future medical device development.

TCT-107

TIARA - A Novel Catheter-Based Mitral Valve Bio-Prosthesis Short Term Pre-Clinical Results

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Background: A significant proportion of patients with severe mitral regurgitation (MR), have severe comorbidities and are not candidates for conventional surgery because of high operative risk. The field of percutaneous mitral valve (MV) repair is developing and many technologies are now under investigation. To date, trans-catheter valve implantation is limited to pulmonary and aortic valve replacement. The aim of our study wad to demonstrate the safety and feasibility of minimally invasive trans-catheter implantation of a novel self-expanding MV specifically designed for the unique complex anatomical configuration of the mitral apparatus - the TIARA self-expanding bioprosthetic valve.
Methods: Using a trans-apical approach, TIARA valves were successfully implanted in 29/36 (81%) domestic swine with fluoroscopic and 3D transesophageal echocardiographic (TEE) guidance. Follow-up varied from 90 minutes to 96 hours. The valves were delivered using a short flexible 30F delivery catheter.
Results: Total procedure time ranged from 17 to 26 minutes, and the prosthesis deployment time ranged from 5 to 13 minutes. In the 29 successful implantations, TEE demonstrated excellent function and alignment of the TIARA prosthesis, with no left ventricular outflow tract obstruction, no pericardial effusion, no encroachment on the aortic valve, and no trans-valvular gradients. Significant paravalvular leaks were only seen in cases of either MV annulus-prosthesis mismatch or failed implantation. Macroscopic evaluation of the explanted hearts demonstrated stable and secure positioning of the valves in all planes of the mitral apparatus with no evidence of injury to the ventricular or atrial walls.
Conclusions: We report our successful initial pre-clinical experience with the TIARA trans-catheter self-expanding mitral bioprosthetic valve. We have demonstrated that the implantation of the TIARA valve is a feasible, safe, and relatively straightforward procedure, which results in a stable and well-functioning mitral valve bioprosthesis. Successful completion of long-term pre-clinical trials of the TIARA is ongoing which will lead the way to human clinical trials.

TCT-108

Performance and Safety of the TRUE Dilatation™ Balloon Valvuloplasty Catheter for Aortic Balloon Valvuloplasty in Patients Undergoing TAVI

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Background: Valvuloplasty (BAV) using the currently available balloons - to prepare the valve annulus for the implant of a transcatheter heart valve - is associated with balloon slippage and rupture in up to 17 % of the cases, which carries an increased risk of stroke. The TRUE Dilatation™ Balloon Valvuloplasty Catheter, constructed of inner and outer film layers that encompass a flexible matrix center embedded with high performance fibers, was developed to allow a fast and precise dilatation of the aortic valve in the absence of balloon rupture. It was aim of the present study to assess the performance of